Next Generation Diagnostic System Increment 1 Deployable Component Industry Day - Addendum

Draft RFP Q&A

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Chemical Biological Medical Systems

Discussion Topics Continued

- **Developer's Tool Kit capability set delivery, SOW para C.3.2.2.8**
- **CP major study areas (Qty 5), SOW para C.3.1.4**
  - IVD Assay Study
  - Environmental Assay Study
  - Environmental Surveillance Non-BWA Assay Development Study
  - Tactical Variant Feasibility Study
  - CLIA Waiver Variant Feasibility Study
- **NGDS Tactical Variant, SOW para C.3.1.4, C.3.2.3.6/.7/.8; C3.3.2.11, C.3.3.2.12, C.3.3.3.7**
- **Open Architecture**
- **Toxin assay development, SOW para C.3.3.3.6.2, C.3.3.3.7**
- **NGDS Performance Specification relevance**

Discussion Areas (Developer's Tool Kit)

- **TD Phase (Option), SOW para C.3.2.2.8**
- **Section L of RFP: "The Offeror shall describe approaches to facilitate the development of new assays by the Government independently of the Original Equipment Manufacturer (OEM) and the range of transition points for optimization, qualification (e.g., FDA clearance) and production of Government developed assays by the Offeror. The intent of this effort is to facilitate the responsive and affordable early development of assays by multiple Government entities working in parallel. Collectively these approaches are referred to as the "Developer's Toolkit".**
- **Deliverable in follow-on TD phase (option), CDRL A0024; will include all technical information, lab equipment, and training materials, other items necessary, to allow the Government to set up alternate assay development sites. (Contractor proprietary information restrictions will be noted in the CDRL paper report.)**
- **The cost associated with setting up at least 1 alternate government assay development site will be included in the contractor's cost proposal associated with SOW C.3.2.2.8.**

Discussion Areas (Developer's Tool Kit)

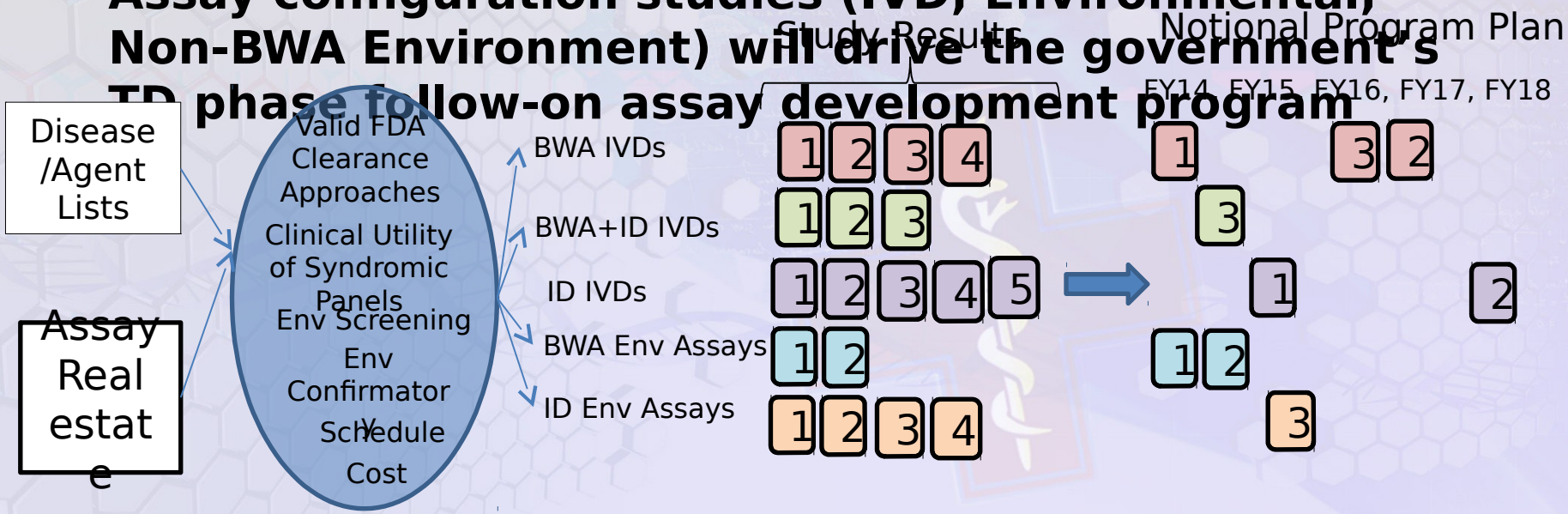
- **Objectives of Developer's Toolkit:**
  - Flexibility for Government organizations develop new BW/Non-BW assays on Contractor's COTS analyzer
  - Mitigation of "closed architectures"
  - Avoid bottlenecks at the vendor for early assay development
  - Ability to leverage the Federal S&T enterprise more efficiently
  - Reduce cost of early assay development
  - Potential for Laboratory Developed Tests (LDTs)
- **Potential Transition Points**
  - Points identified by the Contractor that represent logical inject points in Contractor's workflow leading up to full scale manufacturing
  - Contractor can set the criteria that must be met by the Govt for entry at various transition points
- **Use C.3.2.3.1-C.3.2.3.4 and C.3.3.3.1-C.3.3.3.4 to complete assay development from transition point onward**

Discussion Areas (CP Major Study Areas)

- **CP major study areas (Qty 5), SOW para C.3.1.4**
  - IVD Assay Study
  - Environmental BWA Assay Study
  - Environmental Non-BWA Assay Study
  - Tactical Variant Feasibility Study
  - CLIA Waiver Variant Feasibility Study
- **Study deliverables under CDRL A0020**
  - Minimum of 50 pages per study, not more than 75 pages

Discussion Areas
(CP Major Study Areas)

- **Objective of three assay studies is to obtain information on potential assay configurations and cost and schedule to develop within the context of the vendor's specific technical approach, feasibility of clearance approaches (inclusion criteria, available specimens) and test approaches and the mission to be performed.**
- **Assay configuration studies (IVD, Environmental, Non-BWA Environment) will drive the government's TD phase follow-on assay development program**



Discussion Areas (CP Major Study Areas – Cont'd)

- **Tactical Variant Feasibility and CLIA Waiver Study, SOW paragraph C.3.1.4**
- **NGDS Tactical Variant is a candidate for JBTDS program (one of many) (SOW para C.3.1.4, C.3.2.3.6/.7/.8; C3.3.2.11, C.3.3.2.12, C.3.3.3.7)**
  - Government is trying to achieve development and lifecycle sustainment economies by having common assay consumables with the NGDS COTS design
  - Feasibility study only in CP Phase
  - Alpha Prototype demonstration and Bata Prototype deliveries in TD Phase, if design is acceptable to JBTDS program office
  - Government is trying to achieve development and lifecycle sustainment economies by having common assay consumables with the NGDS COTS design
- **CLIA Waiver Variant Feasibility Study**
  - Determine if modifications to the Contractor's NGDS COTS design are possible to meet CLIA waiver requirements

Discussion Areas (Toxin Assay Development)

- **Chemical, Radiological and Toxin Assay Development (Option) SOW paragraph C.3.3.3.6**
  - Option in NGDS PD Phase
  - The Government will not start Chem, Rad or Toxin assay development efforts until validated Government Furnished Information (GFI) on potential assay designs is available to provide to the vendor, similar to what is provided for BWA assay designs.
  - When pricing Chem/Rad/Toxin assay development efforts, the contractor can assume that assay development can be based on a large multi-target assay development profile

Discussion Areas (NGDS Performance Specification)

- **NGDS Performance Specification is used for source selection only. There is no plan to "build to" this spec after contract award. Section L and M are intended to assess the *degree* which the vendors current COTS system meets the spec.**
- **Section L**
  - "The Offeror shall provide a written narrative demonstrating the degree to which the Offeror's Commercial system is conforms with the NGDS Increment 1 Performance Specification (Section J Attachment X). The Offeror's written narrative shall be organized in accordance with the Performance Specification and show a thorough understanding of the Performance Specification. Each Metric in the performance specification is labeled [C] Critical, [I] Important or [D] Desired. The Offeror shall provide sufficient written technical documentation to allow for thorough evaluation of proposal."
- **Section M Technical SUBFACTOR 2 – Performance Specification**
  - The Government will evaluate the Offeror's written narrative demonstrating the degree to which the Offeror's Commercial system conforms to the NGDS Increment 1 Performance Specification. The Performance Specification is a benchmark used by the Government to determine the extent to which the attributes of a commercial product in its current commercial configuration might conform to certain performance specifications considered useful and valuable to the Government ... There are 9 Critical, 38 Important and 15 Desired Metrics listed in the NGDS Performance Specification. In

Standard Environmental Assay Development Profile

Assay Optimization: 125 days	**- Post GFI package to Contractor** **- Performance LOD testing and assay chemistry freeze-drying for room temperature storage**
Contractor Assay Verification Testing (CVT): 270 days	**- Protocol development and performance verification against sample types intersections and performance levels in SOW Enclosures E & F, and P-Spec**
Government DT Testing: 90 days	**- Government independent lab verification of contactor's assay sensitivity and specificity performance claims (all sample types)**
Assay Stability	**- Contractor tests to prove 24-month room temperature**

Standard IVD Kit Assay Development/Clearance Profile

Assay Optimization: 125 days	- From receipt of GFI DTO CB 56 package to Contractor - LOD testing and assay chemistry freeze-drying for room temperature storage
Pre-Clinical Analytical test: 180 to 365 days	- 9 Tests: Template Comparison, Verification of Extraction Method, Infectivity after Purification, LOD, inclusivity/ Exclusivity, Carry-over, Transport Conditions, PCR Inhibitions, Reproducibility
Clinical Trials: 150-180 days	- 4-6 Clinical trial sites, FDA determination
FDA 510-(k) submission: 60 days	- 700+ Pages (summary of Optimization, Pre-Clinicals, Clinical Trials test report, plus package insert, and operator manual)
FDA Clearance: 90 days	- FDA standard review window